

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the results of tibia intercondylar eminence fracture fixation between headed and headless screws

#### Protocol summary

##### Study aim

Comparison of Fixation outcome of Intercondylar Fracture of Tibia Aminens between Sardar and Headless Screws

##### Design

The clinical trial with control group without blinding, phase 3 will be performed on 80 patients with intercondylar eminence fracture of the tibia. Patients will be randomly assigned to two parallel groups of 40 using the Excel Rand function. In one group, the intercondylar eminence fracture of tibia will be fixed with headed screw. In the other group, a headless screw will be used to fix the intercondylar eminence fracture of the tibia.

##### Settings and conduct

This study will be performed on patients with intercondylar eminence fracture of tibia referred to Besat Hospital in Hamadan. no blinding will be done in this study

##### Participants/Inclusion and exclusion criteria

Participants in this study are patients with intercondylar fracture of the tibia. Patients with meniscus and ligament injuries with fractures will not be included in the study

##### Intervention groups

The first group intercondylar fracture will be fixed with headed screw. The second intervention group intercondylar fracture will be fixed with headless screw.

##### Main outcome variables

Fracture union, Leg function including: need or lack of support when standing and bearing weight, ability to climb stairs, ability to gradually bend the knee in a standing position, stability and instability of the knee, swelling and pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151123025202N22**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

##### Registration date

2022-04-18, 1401/01/29

##### Registrant information

###### Name

Abbas Moradi

###### Name of organization / entity

Hamedan University of Medical Of Science

###### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-05, 1401/02/15

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the results of tibia intercondylar eminence fracture fixation between headed and headless screws

##### Public title

Methods for tibia intercondylar eminence fracture

fixation between headed

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Intracondylar fracture of the tibia

#### **Exclusion criteria:**

Comorbidity of meniscus and ligament damage

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

In this study, patients are randomly divided into two groups. 20 balls will be thrown in an opaque bag, which includes 10 white balls and 10 black balls. With each patient, a ball is accidentally removed from the bag. If the color of the ball is white, Herbert screw will be used and if it is black, the cannula screw will be used. After each selection, the ball is returned to the bag

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Hamadan University of Medical Science

##### **Street address**

shahid fahmideh

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838697

#### **Approval date**

2022-04-09, 1401/01/20

#### **Ethics committee reference number**

IR.UMSHA.REC.1401.031

## **Health conditions studied**

### 1

#### **Description of health condition studied**

tibia intercondylar eminence fracture

#### **ICD-10 code**

542.4

#### **ICD-10 code description**

Fracture of lower end of humerus

## **Primary outcomes**

### 1

#### **Description**

Fracture union, leg function (no limping, no need for support while standing and bearing weight, ability to climb stairs, ability to gradually bend the knee in a standing position, stability and instability of the knee, swelling and pain)

#### **Timepoint**

Patients will be evaluated at three time intervals of weeks 4, 8 and 12 after treatment

#### **Method of measurement**

Union with radiography and leg function will be assessed with the Lysholm knee scale questionnaire. This questionnaire measures limping, the need for support while standing and bearing weight, the ability to climb stairs, the ability to gradually bend the knee in a standing position, knee stability and instability, swelling and pain.

### 2

#### **Description**

Fracture union

#### **Timepoint**

Patients will be evaluated at three time intervals of weeks 4, 8 and 12 after treatment

#### **Method of measurement**

Radiography of the fracture site

## **Secondary outcomes**

### 1

#### **Description**

Infection and abscess at the surgical site

#### **Timepoint**

The first and second weeks after surgery

#### **Method of measurement**

Clinical examination of the patient and observation of the surgical site

## **Intervention groups**

### 1

#### **Description**

Intervention group: Fracture fixation with Sardar Herbert

screw

**Category**

Treatment - Devices

**2**

**Description**

Control group: Fracture fixation with headless screw cannula

**Category**

Treatment - Devices

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Besat Hospital

**Full name of responsible person**

Dr Gholamreza Ghorbani Amjad

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Shahid Beheshti Blvd

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Reza Shokohi

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**Web page address**

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Abbas Moradi

**Position**

Coach

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available